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TRANSMITTAL OF APPEAL BRIEF (Small Entity)

Docket No.  
BAF-10703/29

In Re Application Of: Ferree

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/007,477	11/08/2001	D. Comstock	25006	3732	2845

Invention: **ENHANCED SURFACE AREA SPINAL FUSION DEVICES AND ALIGNMENT APPARATUS THEREFOR**

COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:

March 13, 2005

☒ Applicant claims small entity status. See 37 CFR 1.27

The fee for filing this Appeal Brief is: \$250.00

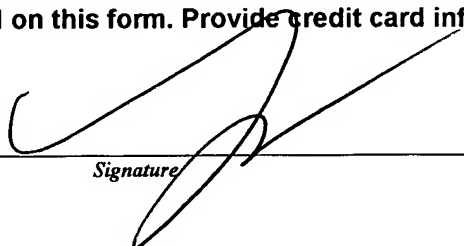
☒ A check in the amount of the fee is enclosed.

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Dated: May 15, 2006

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

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Sheryl Hammer

Typed or Printed Name of Person Mailing Correspondence

CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Ferree

Serial No.: 10/007,477

Group No.: 3732

Filed: November 8, 2001

Examiner: D. Comstock

For: ENHANCED SURFACE AREA SPINAL FUSION DEVICES AND ALIGNMENT  
APPARATUS THEREFOR

**APPELLANT'S BRIEF UNDER 37 CFR §1.192**

Mail Stop Appeal Brief  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**I. Real Party in Interest**

The real party and interest in this case is Dr. Bret A. Ferree, Applicant and Appellant.

**II. Related Appeals and Interferences**

There are no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**III. Status of Claims**

The present application was filed with 10 claims. Claims 4, 6 and 8 have been canceled. Claims 11-17 were added by amendment in July 2004. Claim 5 has been withdrawn from consideration. Claims 7 and 9-11 have been allowed by the Examiner. Claims 1-3, 5, 7 and 9-17 are pending. Claims 1-3 and 12-17 are rejected and under appeal. Claims 1 and 12 are the independent claims under rejection.

**IV. Status of Amendments Filed Subsequent  
Final Rejection**

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No after-final amendments have been filed.

## **V. Summary of Claimed Subject Matter**

Independent claim 1 is directed to an enhanced-surface-area spinal fusion apparatus adapted for use between an upper vertebral body having an inferior vertebral endplate and a lower vertebral body having a superior endplate, the distance between the endplates defining at least one intervertebral spacing. The device comprises a biocompatible fusion device (i.e., 200; 448; 602) having a height which is greater than the intervertebral spacing such that when implanted, at least a portion of the device penetrates into one or both of the upper and lower vertebral bodies. A fastener (630) is configured to extend through the device and the vertebral body into which the fusion device extends, and a separate, removable guide (604, 610) is used for drilling and installation of the fastener. (Specification, page 11, line 5 to page 12, line 10; Figures 6A-D).

Independent claim 12 is also directed to an enhanced-surface-area spinal fusion apparatus adapted for use between an upper vertebral body having an inferior vertebral endplate and a lower vertebral body having a superior endplate, the distance between the endplates defining at least one intervertebral spacing. The device comprises a biocompatible fusion device (i.e., 200; 448; 602) having a lateral surface and a height which is greater than the intervertebral spacing such that when implanted. At least a portion of the device penetrates into one or both of the upper and lower vertebral bodies, and a fastener (630) extends through at least a portion of at least one of the vertebral bodies and into the lateral surface of the fusion device. (Specification, page 11, line 5 to page 12, line 10; Figures 6A-D).

## **VI. Grounds of Objection/Rejection To Be Reviewed On Appeal**

A. The rejection of claims 1-3, 7<sup>1</sup> and 12-17 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,558,423 to Michelson.

## **VII. Argument**

A. Claim 1-3 wherein claims 2-3 stand/fall with claim 1.

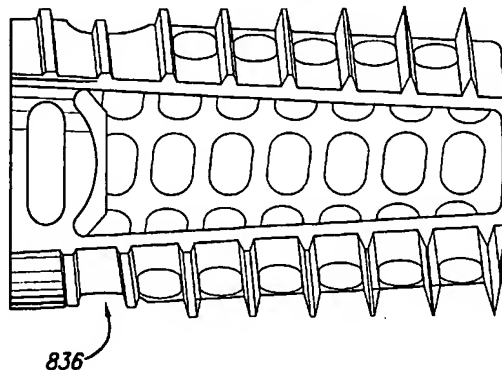
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<sup>1</sup> Although claim 7 was listed in the rejection, it appears from the record that claim 7 was allowed by the Examiner, as stated on page 3 of the December 13, 2005 final Office Action. Accordingly, claim 7 will not be discussed in this section.

Claim 1 stands rejected under 35 USC 103(a) over Michelson (6,558,423). Claim 1 includes, among other limitations, "a separate, removable guide for drilling and installation of the fastener." While conceding that "Michelson does not explicitly disclose the removability of the guide, defined by the lateral surface and corresponding aperture," the Examiner contends that it would have been obvious to provide the implant of Michelson with removable guides because "it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art," citing Nerwin v. Erlichman, 168 USPQ 177, 179. Appellant disagrees.

First, Nerwin v. Erlichman does not "hold" that "constructing a formerly integral structure in various elements involves only routine skill in the art." This Board has previously found "no such holding" in Nerwin v. Erlichman (See, for example, *Ex Parte* James M. Gruden and Robert B. Brooks, Appeal No. 97-1147, attached) "The only statement in that case which we think may be referred to by the examiner is one which indicates that "[t]he mere fact that a given structure is integral does not preclude its consisting of various elements. This statement, in our view, is a construction of the term 'integral,' and does not appear to stand for the proposition the Examiner now urges."

In fact, obviousness under §103 is a legal conclusion based on *factual evidence* (*In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988)). The subjective opinion of the Examiner as to what is or is not obvious, without *evidence* in support thereof, does not suffice. The Examiner advances the argument that Michelson sets forth "a guide 836" but "836" is *a hole through the implant itself*, as shown below:



Column 17, lines 46 to 58 of Michelson read as follows:

“In a preferred embodiment of implants 800, 900 the start of the external thread about the perimeter of the implant is precisely indexed such that if the surgeon knows the depth of the bore created, he may select an implant of the desired length being less than or equal to the depth of the bore created and by starting the insertion of the implant in a preferred rotational alignment such as the desired final rotational alignment the implant when threaded in fully will come to rest such that trailing end 804, 904 will be correctly rotationally aligned so that the screw receiving holes 834, 836, 934, 936 will be oriented correctly towards the adjacent vertebral bodies while the profile of trailing ends 804, 904 will correspond to the contour of the anterior vertebral body.” (Emphasis added.)

Now, since 836 is not a *guide*<sup>2</sup> but a *hole*, how exactly can a hole be *removable*? Answer: It cannot. Indeed, if the hole 836 of Michelson were removed, the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose. As such, there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Since the Examiner has not provided a sufficient factual basis which is supportive of his position, *prima facie* obviousness has not been established. (See also *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968))

B. Claim 12-17 wherein claims 13-17 stand/fall with claim 12.

Claim 12 stands rejected under 35 USC 103(a) over Michelson (6,558,423). Claim 12 include the limitation of “a fastener configured to extend through at least a portion of at least one of the vertebral bodies and into the lateral surface of the fusion device.” The Examiner’s argument is that the implant of Michelson “includes a threaded fastener 842 configured to extend through the implant 800 and the vertebral body (see Figures 52 and 53).” Those figures are reproduced herein below. One fastener is visible in Figure 52; two diverging fasteners are visible in Figure 53.

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<sup>2</sup> The Examiner also advances the argument “[t]hat independent claim 1 has been narrowed in its scope by Applicant ... to overcome the Michelson ... also suggests that an aperture can be reasonably considered a guide.” This misses the point. First, there is no evidence of record that Applicant narrowed claim 1 “to overcome the Michelson.” Second, whatever Applicant does to a claim does not constitute requisite factual evidence or the way in which one of skill in the art would interpret a claim. Third, whether or not “an aperture can be reasonably considered a guide,” says nothing about Applicant’s recitation of a separate, removable element.

FIG. 52

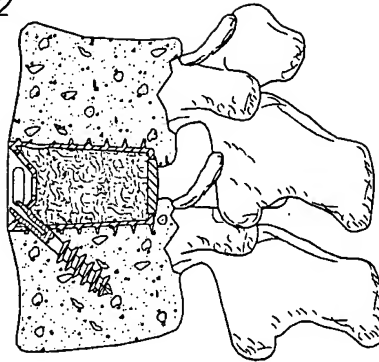
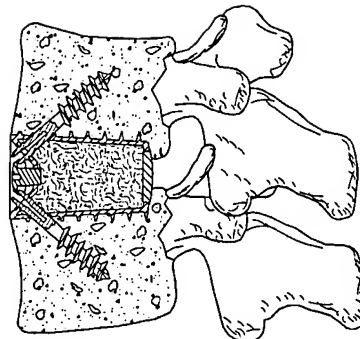


FIG. 53



The Examiner's statement that "Michelson includes a threaded fastener ... configured to extend through the implant and the vertebral body" is absolutely true. The problem is that this observation does not track Appellant's claim language which requires "a fastener configured to extend ... into the lateral surface of the fusion device." The fasteners of Michelson clearly extend only through the *anterior portion* of the implant. The Examiner does not really address this point of difference. The Examiner only argues that "Michelson does not explicitly disclose the removability of the guide, defined by the lateral surface and corresponding aperture," then concludes that it would have been obvious to provide the implant of Michelson with "removable guides," citing Nerwin v. Erlichman. This has nothing to do with a lateral orientation.

Nor would it be obvious to "convert" Michelson's teachings to accommodate the approach of Appellant because *there is no factual evidence* of any kind in support of such an argument. Even though the Examiner wants to call the hole 836 in Michelson's implant a "removable guide," it is always oriented *anterior-to-posterior*. There is no disclosure or suggestion to "move" hole 836 to the lateral side of the implant. A *prima facie* case of obviousness is established by presenting evidence that the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the references before him to make the proposed modification. See In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). The conclusion that the claimed subject matter is *prima facie* obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to modify the relevant teachings of a reference to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Rejections based on §103 must rest on a factual

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basis with these facts being interpreted without hindsight reconstruction of the invention from the prior art. The examiner may not, because of doubt that the invention is patentable, resort to speculation, unfounded assumption or hindsight reconstruction to supply deficiencies in the factual basis for the rejection. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). "Mere denials and conclusory statements are not sufficient to establish a genuine issue of material fact." Dembiczak, 175 F.3d at 999-1000, 50 USPQ2d at 1617, citing McElmurry v. Arkansas Power & Light Co., 995 F.2d 1576, 1578, 27 USPQ2d 1129, 1131 (Fed. Cir. 1993). The Examiner has failed to establish *prima facie* obviousness.

### **Conclusion**

In conclusion, for the arguments of record and the reasons set forth above, all pending claims of the subject application continue to be in condition for allowance and Appellant seeks the Board's concurrence at this time.

Respectfully submitted,

By: \_\_\_\_\_

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Date: May 15, 2006

**APPENDIX A****CLAIMS ON APPEAL**

1. Enhanced-surface-area spinal fusion apparatus adapted for use between an upper vertebral body having an inferior vertebral endplate and a lower vertebral body having a superior endplate, the distance between the endplates defining at least one intervertebral spacing, the device comprising:

a biocompatible fusion device having a height which is greater than the intervertebral spacing such that when implanted, at least a portion of the device penetrates into one or both of the upper and lower vertebral bodies;

a fastener configured to extend through the device and the vertebral body into which the fusion device extends; and

a separate, removable guide for drilling and installation of the fastener.

2. The apparatus of claim 1, wherein the fusion device includes an aperture adapted to receive the fastener.

3. The apparatus of claim 1, wherein the fastener is threaded.

12. Enhanced-surface-area spinal fusion apparatus adapted for use between an upper vertebral body having an inferior vertebral endplate and a lower vertebral body having a superior endplate, the distance between the endplates defining at least one intervertebral spacing, the device comprising:

a biocompatible fusion device having a lateral surface and a height which is greater than the intervertebral spacing such that when implanted, at least a portion of the device penetrates into one or both of the upper and lower vertebral bodies; and

a fastener configured to extend through at least a portion of at least one of the vertebral bodies and into the lateral surface of the fusion device.

13. The apparatus of claim 12, wherein the lateral surface of the fusion device includes an aperture adapted to receive the fastener.
14. The apparatus of claim 12, wherein the fastener is threaded.
15. The apparatus of claim 12, further including a guide for the insertion of the fastener.
16. The apparatus of claim 15, wherein the guide is mountable on the fusion device.
17. The apparatus of claim 15, wherein guide may be used for drilling and installation of the fastener.

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**APPENDIX B**

**EVIDENCE**

None.

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**APPENDIX C**  
**RELATED PROCEEDINGS**

None.



THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today  
(1) was not written for publication in a law journal and  
(2) is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte JAMES M. GRUDEN and ROBERT B. BROOKS JR.

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Appeal No. 97-1147  
Application 08/349,087<sup>1</sup>

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ON BRIEF

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Before FRANKFORT, McQUADE and CRAWFORD, Administrative Patent Judges.

FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 4 and 7. Claims 13 through 15, the only other claims remaining in the application, stand allowed.

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<sup>1</sup>Application for patent filed December 2, 1994.

Appeal No. 97-1147  
Application 08/349,087

Claims 1 through 3, 5, 6, 8 through 12 and 16 through 18 have been canceled.

Appellants' invention is directed to a centrifugal clutch for use in a power door lock actuator. A copy of independent claims 4 and 7 on appeal may be found in the Appendix to appellants' brief.

The sole prior art reference of record relied upon by the examiner as evidence of obviousness of the claimed subject matter is:

Kagiyama et al. (Kagiyama)	4,520,914	Jun. 04,
1985		

Claims 4 and 7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Kagiyama.

Reference is made to the final rejection (Paper No. 8, mailed April 22, 1996) and to the examiner's answer (Paper No. 15, mailed October 16, 1996) for the examiner's full reasoning in support of the above-noted rejection. A complete exposition of appellants' arguments thereagainst are found in the appeal

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Application 08/349,087

brief filed August 26, 1996 (Paper No. 13).

OPINION

After careful consideration of appellants' specification and claims, the teachings of the applied Kagiya reference and the arguments and comments advanced by appellants and the examiner,

it is our determination that the examiner's conclusion of

obviousness regarding the claimed subject matter is unsupported by the applied prior art and will therefore not be sustained.

The Kagiya patent discloses a centrifugal clutch arrangement for use in a power door lock actuator. Using the language of appellants' claim 4 on appeal, we note that the clutch of Kagiya (Figs. 2-6) includes a rotatable driven member (4), a rotatable driver (5), a recess (53) in the driver, and a permanent magnet slider element (6) slidably retained in the recess and operable for selectively establishing a positive driving connection between said driver

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and said driven member. A rotary drive shaft (21) of the motor (2) is inserted into the driver (5) and attached thereto. The drive shaft (21) is made of a magnetic material. As noted in column 2, lines 20-30,

"[w]hen the clutch body is not driven the permanent magnet is moved toward the rotary drive shaft due to the magnetic attraction therebetween and is accommodated within the retaining hole. When the clutch body is being driven at a certain speed, the permanent magnet is released from the rotary drive shaft by the centrifugal force of the clutch body, projects toward the inner wall of the clutch drum and is engaged with an engaging protuberance provided in the clutch drum with the result that the rotation of the clutch body is transmitted to the clutch drum."

As the examiner has recognized (final rejection, page 4), Kagiya does not disclose a magnetic decoupling means of the type required in appellants' claims 4 and 7 on appeal for selectively magnetically breaking the positive driving connection between the driver (5) and the driven member (4). More specifically, the clutch of Kagiya does not include a permanent magnet "secured within said driver for magnetically attracting said slider in a direction away from said driven member, and wherein said slider is located between said

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permanent magnet and said driven member," as indicated in claim 4 on appeal, and in similar language in claim 7 on appeal. To address this difference, the examiner has taken the position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the permanent magnet slider (6) of Kagiyaama "a separate member from the magnet, since it has been held that constructing an integral structure into various elements involves only routine skill in the art" (final rejection, page 4). To account for the plural sliders set forth in claim 7 on appeal, the examiner urges that it would have been obvious to one of ordinary skill in the art at the time the invention was made to have plural sliders in the clutch mechanism of Kagiyaama, "since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art" (final rejection, page 4).

In contrast with the examiner's position, we find nothing in the Kagiyaama patent which provides any teaching, suggestion or incentive which would have motivated one of ordinary skill in the art to make the particular selective modifications in

the

centrifugal clutch therein as proposed by the examiner. The mere

fact that one of ordinary skill in the art, once informed of the desirability of making a magnetic decoupling means of the type defined in appellants' claims on appeal, could achieve this result through the application of routine skill in the art, provides no evidence that such a modification would have been obvious to those of ordinary skill in the art at the time of appellants' invention, absent reliance upon appellants' own disclosure. Moreover, as appellants have pointed out on page 11 of their brief, the examiner's proposed modification of the clutch in Kagiya would appear to be contrary to the express teachings of that patent regarding the desired simplicity of construction, reduced numbers of parts, and inexpensive manufacturing discussed therein (see Col. 1, lines 21-25 of Kagiya).

From our perspective, only hindsight based on appellants' own teachings would have provided any reason for one of ordinary skill in the art to consider a modification in the

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centrifugal clutch of Kagiya of the nature urged by the examiner in the rejection before us on appeal so as to arrive at the clutch assembly defined in appellants' independent claims 4 and 7. This

being the case, we will not sustain the examiner's rejection of claims 4 and 7 under 35 U.S.C. § 103 based on the teachings of Kagiya.

The examiner's reliance on and citation of Nerwin v. Erlichman, 168 USPQ 177, 179 (Bd.Pat.Int. 1969), which according to

the examiner held that "constructing a formerly integral structure in various elements involves only routine skill in the art," appears to us to be misplaced. We find no such "holding" in Nerwin v. Erlichman. The only statement in that case which we think may be referred to by the examiner is one which indicates that

"[t]he mere fact that a given structure is integral does not preclude its consisting of various elements."

This statement, in our view, is a construction of the term "integral," and does not appear to stand for the proposition the

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examiner now urges.

In light of the foregoing, we must agree with appellants' position that the examiner has failed to make out a prima facie case of obviousness under 35 U.S.C. § 103. A rejection based on §103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty

of supplying the factual basis for the rejection he advances. The examiner may not, because he (or she) doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual

basis. See In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967). Since in this case there is an inadequate factual basis to support the examiner's rejection of appellants' claims 4 and 7 under 35 U.S.C. § 103, we are compelled to reverse that rejection.

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REVERSED

CHARLES E. FRANKFORT	)	
Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
JOHN P. McQUADE	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
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MURRIEL E. CRAWFORD	)	
Administrative Patent Judge	)	

Appeal No. 97-1147  
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